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REMARKS

This Amendment is responsive to the Office Action dated September 13, 2006. Applicant has amended claims 1, 15, 30, 32, 39, 42, and 47, and canceled claims 2 and 48. Claims 1, 3-8, 10-34, 36-45, 47, 49, 51, 53-56, and 60-66 are pending.

Claim Rejections Under 35 U.S.C. § 112 and Claim Objections

In the Office Action, claims 15, 32, and 39 were objected to because of inadvertent typographical errors existing in the claims. As to claim 15, the Office Action suggested changing the third line from "and provides the sloped transition" to "and provides a sloped transition" so as to avoid an antecedent basis problem. Applicant notes, however, that claim 15 depends from claim 1, which recites, "a sloped transition." Therefore, "the sloped transition" in claim 15 has a proper antecedent basis. However, Applicant has amended claim 15 to include a proper antecedent basis for the "sloped interface element." Applicant has also amended claims 32 and 39 to incorporate the Examiner's suggested changes. Applicant respectfully requests that the objections to claims 15, 32, and 39 be withdrawn.

In the Office Action, the Examiner rejected claim 42 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 42 for purposes of clarification. Applicant submits that claim 42, as amended, particularly points out and distinctly claims the subject matter, as required by 35 U.S.C. § 112, second paragraph.

Claim Rejection Under 35 U.S.C. § 101

In the Office Action, the Examiner rejected claim 30 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Applicant has amended claim 30 in accordance with the Examiner's recommended changes. Applicant submits that claim 30, as amended, is directed to statutory subject matter under 35 U.S.C. § 101.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, claims 1-4, 12-14, 18, 47-48, 63, and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Singer et al. (U.S. Patent No. 5,638,832). Claims 1, 5, 7, 10-14, 18-19, 21, 31, 47, 51, 63, and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Probst et al. (U.S. Patent No. 7,103,415). Claims 1, 2, 5, 10, 12-14, 23-25, 47-48, 51, and 53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muto (U.S. Patent No. 4,094,321). Claims 3-4, 6, 20, 22 and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muto in view of Bardy et al. (U.S. Patent No. 6,788,974). Claims 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muto in view of Loeb et al. (U.S. Patent No. 6,214,032). Claims 27 and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muto in view of Sanchez-Zambrano (U.S. Patent No. 5,895,414).

Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Independent claim 1 has been amended to clarify that an overmold of an implantable medical device (IMD) is at least partially flexible and comprises a motion reduction element to provide structural integrity to the IMD. In particular, independent claim 1 as amended recites an IMD comprising a plurality of interconnected modules, each comprising a respective one of a plurality of housings, and an overmold that at least partially encapsulates each of the housings, where the overmold is at least partially flexible and includes a motion reduction element to reduce intermodule motion and to provide structural integrity to the IMD, where a portion of the IMD is tapered to provide a sloped transition between an edge of the IMD and a surface of a patient, an angle between the edge of the IMD and the surface of the patient being greater than 90 degrees.

The applied references lack any teaching that would have suggested each and every element of claim 1 as amended. For example, the applied references fail to teach or suggest an implantable medical device comprising a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings, and an overmold that at least partially encapsulates each of the housings and includes a motion reduction element to reduce

intermodule motion and provide structural integrity to the implantable medical device. The Office Action concluded that the electronic coupling (20) in Singer et al., the lead (34) in Probst et al., and the bottom wall (43) of a hollow casing (42) in Muto et al. are each motion reduction elements. Applicant respectfully disagrees.

With respect to Singer et al., the Office Action reasons that the electronic coupling (20) reduces intermodule motion because it "connects the [control module (12) and display device (14)] together and doesn't allow them to move apart from one another." (Office Action at page 5, item 11.) Applicant agrees that the electronic coupling in Singer et al. electrically couples the control module with the display device. However, Applicant disagrees with the Office Action's conclusion that the electronic coupling is a motion reduction element because the electronic coupling in no way provides structural integrity to the subcutaneous implant (10) to reduce intermodule motion.

Each and every claim term must be given meaning, and the claimed invention as a whole must be considered. MPEP § 2141.02. Claim 1 clearly recites a plurality of interconnected modules, where the motion reduction element reduces intermodule motion. Thus, the motion reduction element reduces motion between interconnected modules. The Office Action's interpretation of the motion reduction element fails to give meaning to the claim term "interconnected." Interconnected modules inherently cannot move apart from each other due to their interconnected state. Thus, the fact that the electronic coupling in Singer et al. may connect modules together and prevent them from moving apart from one another does not necessarily qualify the electronic coupling as a motion reduction element. Rather, as Applicant's disclosure provides, a motion reduction element reduces intermodule motion by providing sufficient structural integrity to the implantable medical device to restrict relative motion between modules to a certain degree or within certain ranges. (Applicant's disclosure at paragraph 48.) Claim 1 has been amended to clarify that the motion reduction element provides structural integrity to the implantable medical device.

The electronic coupling taught by Singer et al. is not a motion reduction element, as the term is used in Applicant's disclosure, because the electronic coupling does not provide any structural integrity to the subcutaneous implant and does not reduce motion between interconnected modules. The electronic coupling only interconnects the control module and the

display device. Singer et al. makes no mention of the possibility that the electronic coupling may provide structural integrity to the subcutaneous implant, but merely teaches that its electronic coupling is "one or more wires or fiber optic links, or simply a direct plug-type connection." (Col. 3, ll. 4-6.)

Furthermore, even though Singer et al. mentions in passing that its device may be encapsulated in a biologically-inert capsule, which the Office Action interpreted as being an overmold, Singer et al. does not suggest that this capsule may comprise the electronic coupling. Accordingly, even if Singer et al. teaches an IMD comprising interconnected modules and the electronic coupling is a motion reduction element, Singer et al. does not teach or suggest an IMD comprising an overmold comprising a motion reduction element.

Similarly, Probst et al. does not teach or suggest a motion reduction element to reduce intermodule motion and provide structural integrity to the IMD. In fact, Probst et al. does not even teach or suggest a plurality of interconnected modules that each comprise a respective housing. The Office Action states that the electrochemical cell (12)and control circuitry (32) are two separate modules that are interconnected by lead 34, which is "synonymous with Applicant's 'motion reduction element . . .' since lead 34 keeps the two modules 12 and 32 connected to each other and unable to move apart." (Office Action at page 8, item 16.) Applicant respectfully disagrees with this analysis of Probst et al.

Electrochemical cell (12) and control circuitry (32) are not two separate modules each comprising a respective one of a plurality of housings, as required by Applicant's claim 1. While the Office Action admits that Probst et al. is silent as to whether control circuitry is disposed within a housing, the Office Action goes on to conclude that, "it is inherent or at least obvious to one having ordinary skill in the art that module 32 also comprising a housing to protect . . . electrical components that exist within the module 32." (Id.) However, the Office Action does not provide any support that it is well known in the electrical arts to enclose control circuitry in its own housing, and nothing in Probst suggests modifying the control circuitry to include a housing to protect components of the control circuitry. The Office Action does not even indicate what the electrical components would be protected from, and so it is unclear why one would be motivated to modify the Probst et al. control circuitry to include a housing.

The Court of Appeals for the Federal Circuit recently addressed the evidentiary standard required to uphold an obviousness rejection.[1] Specifically, the Federal Circuit stated: "[the] factual question of motivation is material to patentability, and (can) not be resolved on subjective belief and unknown authority.[2] This finding must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.[3] Deficiencies in the evidentiary record cannot be cured by general conclusions such as "general knowledge" or "common sense."[4] Accordingly, the Examiner cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.[5] Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to modify the control circuitry in the Probst et al. device to include a housing, the rejection to claim 1 in view of Probst should be withdrawn. The implantable medical device taught by Probst et al. includes a single housing (36) that encloses the control circuitry and an electrochemical cell, which the do not have separate housings, and accordingly does not meet the limitations of Applicant's claim 1.

Even if the control circuitry and electrochemical cell of the Probst et al. device were separate modules including respective housings, Probst et al. does not teach or suggest a motion reduction element that reduces intermodule motion and provides structural integrity to the device. The lead (34) interconnecting the electrochemical cell and control circuitry in Probst et al. is not a motion reduction element, as the Office Action asserts. Just as with the electronic coupling in the Singer et al. reference, the lead in the Probst et al. reference merely electrically couples two components, and in no way provides structural integrity to the IMD. Probst et al. does not teach or suggest that the lead 34 may help reduce motion between the electrochemical cell and the control circuitry, much less that the lead 34 may be configured to provide structural integrity to the implantable device. In fact, it is not even clear why the lead would be configured to provide structural integrity to the implantable device because both the electrochemical cell and the

[1] *In re Lee*, 61 USPQ2d 1430, (Fed. Cir. 2002).
[2] *Id.* at 1434.
[3] *Id.*
[4] *Id.*
[5] *Id.*

control circuitry are disposed in a single, rigid casing. (Probst et al. at col. 2, ll. 24-26.) In addition, Probst does not teach or suggest an overmold that is at least partially flexible, as amended claim 1 recites. Thus, Probst et al., alone or in combination with the other references, fails to teach or suggest each and every element of claim 1.

The Office Action also looked to Muto as teaching a plurality of interconnected modules each comprising a respective one of a plurality of housings, and an overmold that includes a motion reduction element to reduce intermodule motion. More specifically, the Office Action found that the self-contained power supply (31) and pulsation control circuitry (32) in Muto were interconnected modules, and seemed to suggest that the bottom wall (43) of a hollow casing (42) was a motion reduction element. (Office Action at page 11, item 25.) Muto, alone or in combination with the other cited references, does not teach or suggest each and every element of claim 1 as amended.

First, Applicant notes that Muto does not teach or suggest an overmold that is at least partially flexible, as amended claim 1 recites. Second, Applicant respectfully disagrees with the Office Action's interpretation of the sentence, "self-contained power supply 31 and pulsation control circuitry 32 . . . " at column 2, lines 37-38 of Probst et al. In particular, Applicant takes the position that "self-contained" modifies "power supply," but not "pulsation control circuitry," and therefore, Muto does not teach or suggest a plurality of interconnected modules each comprising a respective one of a plurality of housings, as recited by Applicant's claim 1. Furthermore, even if Muto taught a self-contained power supply and a self-contained control circuitry, nothing in Muto suggests that the power supply and circuitry are enclosed within separate housings or are interconnected.

The Office Action seems to suggest that the bottom wall of the device casing both interconnects the "modules" and is a motion restriction element to limit intermodule motion. In particular, the Office Action takes the position that, "it is inherent or at least obvious that one or both of the modules 31 and 32 are glued or mounted to the bottom wall 43 of the overmold 42." (Office Action at page 11, item 25.) Applicant respectfully disagrees. Muto is silent as to the arrangement of the power supply and control circuitry within the device, and makes no mention of how the power supply and control circuitry are held within the device. Furthermore, if the Office Action was correct and one, but not both, of the modules was glued or mounted to the

bottom wall of the casing, it is unclear how the "modules" would be considered to be "interconnected," as required by Applicant's claim 1.

As established above, deficiencies in the evidentiary record cannot be cured by general conclusions such as "general knowledge" or "common sense."[6] Accordingly, the Examiner cannot rely on the unsupported, conclusory statement that it would have been inherent or obvious to mount the power supply and/or control circuitry to a bottom wall of a device casing to close holes in the evidentiary record.[7]

Independent claim 47 as amended recites an implantable medical device that comprises a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings, and means for integrating the modules into a single structure that at least partially encapsulates each of the housings, wherein the means is at least partially flexible and comprises means for reducing intermodule motion. For at least the reasons given above for independent claim 1, the cited references fail to teach or suggest each and every element of independent claim 47.

Applicant respectfully traverses the rejections to dependent claims 3-7, 10-14, 18-25, 27-29, 31, 49, 51, 53, 55, 63, and 66 under 35 U.S.C. § 103(a). The Sanchez-Zambrano, Bardy et al., and Loeb et al. references fail to provide any teaching sufficient to overcome the basic deficiencies of the Singer et al., Probst et al., and Muto references. Claims 3-7, 10-14, 18-25, 27-29, 31, 48, 49, 51, 53, 55, 63, and 66 are dependent upon Applicant's independent claims, and, accordingly, are also patentable over the cited references. In view of the fundamental deficiencies evident in the cited references, it is not necessary to discuss in detail the additional patentable differences presented by the remaining dependent claims. In reserving comment, however, Applicant neither admits nor acquiesces in the Examiner's interpretation with respect to the teachings in such applied references or with respect to any features set forth in the dependent claims.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1, 3-7, 10-14, 18-25, 27-29, 31, 47, 49, 51, 53, 55, 63, and 66 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

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[6] *Id.*
[7] *Id.*

Rejection for Obviousness-type Double Patenting:

The Examiner provisionally rejected claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 (amended November 16, 2005) of copending Application No. 10/731,638. The Examiner provisionally rejected claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 and 26-31 (amended June 27, 2006) of copending Application No. 10/731,867.

The Examiner provisionally rejected claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 and 33-57 (amended November 28, 2005) of copending Application No. 10/731,869. The Examiner provisionally rejected claims 1-8, 12-22, 31, 32-34, 36, 39-41, 45, 47-49, 56, 60-61, 63, 64 and 66 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/731,881.

Applicant respectfully traverses the provisional rejections. Applicant respectfully submits that the Examiner has not established a prima facie case of obviousness-type double patenting. To support an obviousness-type double patenting rejection, the Examiner must assess the differences between the claims in the pending application and the claims in the issued patent (or in the present case, in the co-pending patent applications). *In re Berg*, 46 USPQ2d 1226, 1229 (Fed Cir. 1998). In particular, the Examiner should indicate why the claims in an application are obvious over the claims in the granted patent. *Id.*

With respect to the provisional rejections in view of Application Nos. 10/731,638, 10/731,867, and 10/731,869, the Examiner concluded that, "although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are a broadening of the scope of the claims presented in [Application Nos. 10/731,638, 10/731,867, and 10/731,869] or an obvious variant thereof. The Examiner makes reference to the Applicant's disclosure . . . where it is specified that the 'motion reduction element' is synonymous with one that allows multiple degrees of movement along multiple axes to occur between the modules."

Applicant respectfully disagrees with the Examiner's interpretation of Applicant's disclosure. At the cited portion of Applicant's disclosure, Applicant makes clear that the motion reduction element allows "free inter-modular motion within one of the degrees within a range." (Emphasis added.) As indicated in throughout Applicant's disclosure, including paragraph 48, the motion reduction elements provide sufficient structural integrity to the implantable medical device to restrict relative motion between modules to a certain degree or within certain ranges. In this way, the motion reduction element(s) reduce intermodule motion.

Nothing in the claims of Application Nos. 10/731,638, 10/731,867 or 10/731,869 recite a motion reduction element to reduce intermodule motion. Furthermore, nothing in the claims of Application Nos. 10/731,638, 10/731,867 or 10/731,869 even recites an implantable medical device including a sloped transition between an edge of the device and a surface of the patient.

Applicant respectfully submits that the Examiner has failed to clarify the reasons why one skilled in the art would conclude that the invention defined in the claims at issue would have been an obvious variation of the invention defined in the claims of Application Nos. 10/731,638, 10/731,867 or 10/731,869, as required by Section 804 of the MPEP.

For example, with respect to the rejection of Applicant's independent claim 1 over independent claim 1 of copending Application No. 10/731,638, the Examiner failed to provide any reason why an implantable medical device comprising a motion reduction element to reduce intermodule motion, where a portion of the implantable medical device is tapered to provide a sloped transition between an edge of the device an a surface of a patient would have been obvious in view of the programmer recited in claim 1 of Application No. 10/731,638, which does not even recite a motion reduction element or a tapered portion. Specifically, claim 1 of Application No. 10/731,638 recites:

> An implantable medical device for implantation in the head of a patient comprising:
> a first module including a first module housing and first operative component within the first module housing;
> a second module including a second operative component; and
> a flexible overmold that covers the second module and partially covers the first module wherein the first module housing extends out of the overmold for receipt in a first recess in a cranium of a patient.

The claims of Applicant Nos. 10/731,867 and 10/731,869 similarly fail to recite a motion reduction element or a portion that is tapered. The rejection for obviousness-type double

patenting should be withdrawn. If the Examiner maintains the obviousness-type double patenting rejection, however, Applicants respectfully request clarification of the grounds of rejection.

On June 16, 2006, Applicant submitted a Terminal Disclaimer signed by Jason D. Kelly, where the Terminal Disclaimer disclaimed the terminal part of the statutory term of any patent granted on the present application that would extend beyond the term of co-pending Application No. 10/731,881. An Advisory Action mailed on July 14, 2006 indicated that the Terminal Disclaimer was disapproved because Jason D. Kelly, the signing attorney, was not of record. Applicant submits that the Terminal Disclaimer filed on June 16, 2006 is properly signed by an attorney of record. Jason D. Kelly is associated with Customer No. 28863. A Power of Attorney executed by the inventors of the present application and filed on May 18, 2004 appointed the practitioners associated with Customer No. 28863 to prosecute the present application. Accordingly, Jason D. Kelly is an attorney of record, and the Terminal Disclaimer was properly executed by an attorney of record for the present application. Applicants respectfully request reconsideration of the Terminal Disclaimer filed on June 16, 2006.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

December 12, 2006

By: _____

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